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To Whom It May Concern:

I have become aware that the 30 September 1999 issue of the Federal Register relates that the FDA wants to regulate allograft materials as medical devices. Please be advised as I feel this is totally inappropriate. Allograft materials are used throughout orthopaedic surgery and have been used in many cases to supplement fixation devices and speed bone healing. They are not in themselves medical devices. It is apparent to me that many bone banks would not have the resources to satisfy the FDA's premarket requirements and, thus, could endanger the allograft materials that we currently use.

Sincerely

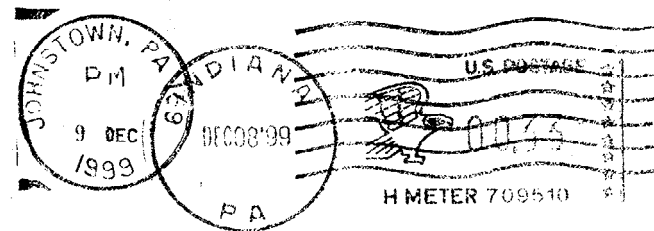
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